REMARKS

The only pending claim is 43. Claim 43 has been amended. The subject matter of this amendment can be found throughout the specification, *inter alia*, at Figure 4B. Claim 44 is hereby canceled without prejudice or disclaimer.

Claim Rejection Under 35 U.S.C. § 112, ¶ 1

The Examiner has rejected claim 43 under 35 U.S.C. § 112, first paragraph, alleging that the claim covers subject matter that is not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. The Examiner states the claim is drawn to treating any TH1-associated condition with ID4, there is no recognition in the art of such a functional role of ID4 in inflammation, and the specification does not teach that ID4 "plays any role whatsoever in the pathology of all TH1 associated diseases."

Applicants respectfully traverse the rejection as being without basis in fact. Nevertheless, solely in order to reduce the issues and expedite allowance hereof, Applicants have amended claim 43 to recite a method of treating a subject afflicted with psoriasis comprising providing ID4 to the cells of the subject.[1]

[1/]Applicants reserve the right to pursue any subject matter removed by way of this amendment, as well as other subject matter disclosed in the specification, in divisional and/or continuation applications.

In this regard, to the extent the Examiner maintains the application provides no guidance as to administering ID4 for treatment of psoriasis (cf., page 2 of the official action, lines 28-29), such is incorrect. Applicants have shown

- ID4 is statistically significantly decreased in expression in psoriatic skin cells as opposed to nonpsoriatic skin cells. *See* page 13, lines 34-35, and Table 8.
- ID4 maps to the psoriatic susceptibility loci. *See* page 13, lines 32-37, Table 7, and Table 12.
- How to treat psoriasis (or a TH1-associated condition) by administering a marker protein of the claims. *See, e.g.,* page 71, lines 10-30.

That ID4 is useful to treat psoriasis is further supported by Applicants' disclosure that changes in gene expression that precede clinical improvement play a causal role in disease progression compared to genes whose expression changes mirror clinical improvement or do not change despite clinical improvement. *See* page 94, lines 20-22. In this regard, the specification correspondingly teaches that ID4 returned to normal or uninvolved levels at time points that preceded clinical improvement following therapeutic intervention with rhIL-11 or cyclosporin A.[2] *See* page 94, lines 22-26; *see also* page 15,

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[2]Many of the genes shown to do so also mapped to the psoriasis susceptibility loci, further showing that modulating the levels of these markers is useful for the treatment of inflammatory diseases generally. *See* page 94, lines 22-27.

lines 20-34, and Figure 7. Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

CONCLUSION

In view of the foregoing remarks, favorable reconsideration and allowance of pending claim 43 is earnestly solicited.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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